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10/579,137	05/15/2006	Jussi Nurmi	TUR-181	3667

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EXAMINER	
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ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,137	NURMI ET AL.	
	Examiner	Art Unit	
	STEPHANIE K. MUMMERT	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on February 2, 2009 is acknowledged and has been entered. Claims 1-17 have been canceled. Claims 18-30 have been added. Claims 18-30 are pending.

Claims 18-30 are discussed in this Office action.

All of the amendments and arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is made FINAL as necessitated by cancellation of the previously rejected claims and introduction of new claims.

New Grounds of Rejection as necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabuz et al. (US Patent 6,568,286; May 2003; 102(e) date, June 2, 2000) in view of Iqbal et al. (Biosensors & Bioelectronics, 2000, vol. 15, p. 549-578). Cabuz teaches a filtration apparatus useful for detection of harmful biological agents (Abstract).

With regard to claim 18, Cabuz teaches a nucleic acid amplification assay for quantitative and/or qualitative analysis of the presence of a specific analyte or specific analytes in a biological sample, which analytes, if present, are contained in biological particles of said sample, said assay comprising

forcing said sample in a first direction through a filter that retains said biological particles, removing biological particles from said filter by a flush flow in a second direction opposite said first direction, and analyzing biological particles contained in said flush flow (col. 2, lines 39-58, where an apparatus is designed to sample fluid such as air, filtering the fluid and sampling the fluid using a sensor and where the apparatus can be used to detect airborne agents or harmful chemical or biological agents; see also col. 9, lines 4-67, where the mesopump sensor can be operated either unidirectionally or bidirectionally and where in the bidirectional embodiment, the mesopump is operated in a measuring mode, forcing air through a filter and the sensor and "at a point where the sensor saturation is believed possible, the pumping direction can be reversed" and that "the purifying mode of operation can be continued until the analyte or other absorbant is believed to have been sufficiently desorbed from the sensor". Therefore, this passage indicates that filter/sensor retains analytes and that the analytes are released during the reverse flow or "flush flow" as claimed).

With regard to claim 19, Cabuz teaches an embodiment of claim 1, further comprising performing an initial filtration which does not retain the biological particles containing the analyte or analytes but retains particles that might interfere with the analysis of the analyte or analytes, said initial filtration being performed prior to forcing said sample in a first direction through a filter which retains said biological particles (col. 2, lines 46-48, where filters can also be included of the "impactor type" to trap particles that have entered the pump).

With regard to claim 20, Cabuz teaches an embodiment of claim 1, wherein said flush flow is analysed for the analyte or analytes without any further purification (col. 9, lines 4-67, where the mesopump sensor can be operated either unidirectionally or bidirectionally and where in the bidirectional embodiment, the mesopump is operated in a measuring mode, forcing air through a filter and the sensor and "at a point where the sensor saturation is believed possible, the pumping direction can be reversed" and that "the purifying mode of operation can be continued until the analyte or other absorbant is believed to have been sufficiently desorbed from the sensor". Therefore, this passage indicates that filter/sensor retains analytes and that the analytes are released during the reverse flow or "flush flow" as claimed; see also col. 10, line 65 to col. 11, line 10, where a bi-directional flow embodiment is digrammed in Figure 8).

With regard to claim 21, Cabuz teaches an embodiment of claim 1, wherein retention of the biological particles containing the analyte or analytes in the filter is dependent on the size of the particles (col. 2, lines 46-48, where filters can also be included of the "impactor type" to trap particles that have entered the pump).

With regard to claim 22, Cabuz teaches an embodiment of claim 1 wherein retention of the biological particles containing the analyte or analytes in the filter is essentially dependent on

the chemical properties of the particle (col. 7 to 8, where a variety of sensors or filters are described which capture or detect analytes dependent on chemical properties of the analyte).

With regard to claim 26, Cabuz teaches an embodiment of claim 1, wherein said flush flow comprises a liquid or gas not contained in said sample (col. 9, lines 4-67, where the mesopump sensor can be operated either unidirectionally or bidirectionally and where in the bidirectional embodiment, the mesopump is operated in a measuring mode, forcing air through a filter and the sensor and "at a point where the sensor saturation is believed possible, the pumping direction can be reversed"; and where the reverse pumps air through the filter that was not part of the original sample).

Regarding claim 18, Cabuz does not teach amplification of the biological agents. Iqbal teaches a variety of biological agents and a variety of techniques for their detection, including amplification (Abstract).

With regard to claim 18, Iqbal teaches analyzing biological particles contained in said flush flow by means of a nucleic acid amplification assay (p. 555, where target amplification techniques are described and include PCR and LCR in addition to a variety of other techniques).

With regard to claim 23, Iqbal teaches an embodiment of claim 18, wherein the biological particles containing the analyte or analytes are selected from the group consisting of prokaryotic or eukaryotic cells or spores or components thereof, viruses or viral particles, complexes comprising protein and/or nucleic acid, and any combination thereof (p. 550, col. 1, where it is noted that biological threat agents can be infectious or toxigenic organisms or simply toxins, including anthrax or plague; see Scheme 1, where bacteria, spores, viruses and toxins are depicted as relevant targets or analytes).

With regard to claim 24, Iqbal teaches an embodiment of claim 6, wherein the biological particles containing the analyte or analytes are selected from the group consisting of bacteria, bacterial cell, plant pollen, mitochondria, chloroplast, cell nuclei, virus, phage, chromosome and ribosome (p. 550, col. 1, where it is noted that biological threat agents can be infectious or toxigenic organisms or simply toxins, including anthrax or plague; see Scheme 1, where bacteria, spores, viruses and toxins are depicted as relevant targets or analytes).

With regard to claim 25, Iqbal teaches an embodiment of claim 1, wherein the means of analysing the analyte or analytes is selected from the group consisting of polymerase chain reaction (PCR), reverse transcriptase polymerase chain reaction (RT-PCR), ligase chain reaction (LCR), proximity ligation assay, nucleic acid sequence based amplification (NASBA), strand displacement amplification (SDA) and any combination thereof (p. 555, where target amplification techniques are described and include PCR and LCR in addition to a variety of other techniques).

With regard to claim 27, Iqbal teaches an embodiment of claim 1 wherein the analyte or analytes are selected from the group consisting of a living and/or dead cell or virus; a peptide, a protein or complex thereof; a nucleic acid; and any combination thereof (p. 550, Scheme 1, where the target analytes are analyzed using nucleic acids or antigens).

With regard to claim 28, Iqbal teaches an embodiment of claim 10, wherein the analyte or analytes comprises living and/or dead cells and/or viruses selected from the group consisting of a mold, a yeast, a eukaryotic cell or organism, a pathogenic virus and a cancer cell (p. 550, col. 1, where it is noted that biological threat agents can be infectious or toxigenic organisms or simply

toxins, including anthrax or plague; see Scheme 1, where bacteria, spores, viruses and toxins are depicted as relevant targets or analytes).

With regard to claim 29, Iqbal teaches an embodiment of claim 10, wherein the analyte or analytes comprises nucleic acids selected from the group consisting of DNA, RNA and any derivative thereof (p. 550, Scheme 1, where the target analytes are analyzed using nucleic acids or antigens).

With regard to claim 30, Iqbal teaches an embodiment of claim 10, wherein the analyte or analytes comprises peptides and/or proteins or complexes thereof selected from the group consisting of a hormone, a growth factor, an enzyme or parts thereof and/or complexes thereof; and any combination thereof (p. 550, Scheme 1, where the target analytes are analyzed using nucleic acids or antigens).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have applied the specific harmful biological agents described in detail by Iqbal to the method of capture and analysis of biological and chemical agents as taught by Cabuz. Cabuz taught generally, "the integrated mesopump sensors can provide a large number of small, lightweight and closely spaced sensors that can be used advantageously to detect airborne agents, including harmful chemical and biological agents or trace amounts of TNT or other explosives" (col. 2, lines 49-53). As taught by Iqbal, "identification of biological threat agents involves recognition of bacteria (vegetative cells and spores) viruses and toxins" (p. 550, col. 2). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to have applied the specific harmful biological agents described in detail by Iqbal

to the method of capture and analysis of biological and chemical agents as taught by Cabuz to achieve capture and detection of analytes with a reasonable expectation for success.

Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the cancellation of the claims and the new ground(s) of rejection applied over the new claims. However, insofar as the arguments apply to the new grounds of rejection, the arguments will be considered.

Applicant traverses the rejection of claims as being anticipated by Cabuz. While this rejection has been withdrawn and an obviousness rejection has been applied, Applicant's arguments over Cabuz remain relevant. Applicant argues "Cabuz fails to disclose these steps of the claimed assay" and that the cited passages "do not disclose or suggest retaining biological particles containing the analytes of interest by a filter. Instead, Cabuz appears to disclose the use of a bi-directional flow to clean filters of particulate contaminants" (p. 6 of remarks). Applicant also argues that the 'shallow breathing' mode does not appear to include filtering the sample at all, and certainly does not retain biological particles containing analyte(s) of interest on a filter (p. 7 of remarks).

These arguments have been considered but are not persuasive because, as noted in the new grounds of rejection stated above, not only does Cabuz teach a shallow breathing bi-directional mode of operation, Cabuz also specifically states at col. 9, lines 4-67, where the mesopump sensor can be operated either unidirectionally or bidirectionally and where in the bidirectional embodiment, the mesopump is operated in a measuring mode, forcing air through a

filter and the sensor and "at a point where the sensor saturation is believed possible, the pumping direction can be reversed" and that "the purifying mode of operation can be continued until the analyte or other absorbant is believed to have been sufficiently desorbed from the sensor". Therefore, this passage indicates that filter/sensor retains analytes and that the analytes are released during the reverse flow or "flush flow" as claimed. Therefore, Applicant's arguments are not persuasive and the rejection has been applied in a new obviousness rejection over Cabuz in view of Iqbal with the reasoning argued above, over the newly cited claims.

Applicant also traverses the rejection of prior claims 1-5 and 9 as being obvious over Cabuz in view of Iqbal. Applicant reiterates the position regarding Cabuz and Applicant summarizes the features of the instant application. Finally, Applicant notes that "neither Cabuz nor Iqbal provide an answer to Iqbal's challenge", However beyond noting that Cabuz does not teach retention of biological particles, Applicant does not address the failure of Iqbal to address the challenge. Therefore, Applicant's arguments are not persuasive for the reasons stated above, over the Cabuz reference.

Conclusion

All claims stand rejected, no claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHANIE K. MUMMERT whose telephone number is (571)272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephanie K. Mummert/
Examiner, Art Unit 1637

SKM
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